UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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RADIUS HEALTH, INC., AND IPSEN PHARMA S.A.S
Plaintiffs
v.
ORBICULAR PHARMACEUTICAL TECHNOLOGIES PRIVATE LIMITED
Defendant
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CIVIL ACTION
No. 22-11546-RGS

BEFORE THE HONORABLE RICHARD G. STEARNS
UNITED STATES DISTRICT JUDGE
MARKMAN HEARING
August 1, 2023

Courtroom No. 21
1 Courthouse Way
Boston, Massachusetts 02210

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P R O C E E D I N G S

THE CLERK: All rise.

(Whereupon, the Court entered the courtroom.)

THE CLERK: Court is open. You may be seated.

This is Civil Action No. 22-11564, Radius and Ipsen versus Orbicular.

Would counsel please identify themselves for the record.

MR. MARANDETT: Good afternoon, your Honor. Eric Marandett from Choate, Hall & Stewart on behalf of the plaintiffs, Radius and Ipsen. And with me also from Choate are Bryanna McGillycuddy, Sophie Wang and Sara Ellis.

Ms. Wang and Ms. McGillycuddy will be presenting the arguments today.

And then I also just want to introduce from Radius the Chief Patent Counsel and Senior Patent Counsel, Jim Harrington and Melissa Brand.

THE COURT: Welcome.

MS. RAJWANI: Good afternoon, your Honor. Catherine Rajwani from Harbor Law Group. I'm here on behalf of the defendant, Orbicular Pharmaceutical Technologies, as local counsel.

MR. POLLACK: Good afternoon, your Honor. I'm Alan Pollack of the Windels Marx firm, also on behalf of Obicular. And with me is Christopher Redwood, also of the

Windels Marx firm, and I will be presenting on behalf of Orbicular.

THE COURT: All right.

Before the Court on a fairly narrow issue, which, of course, is the *Markman* claim construction phase of the case there aren't that many terms; in fact, a mercifully small number of terms that are actually being disputed.

As I understand it, what we're looking at is a method patent that deals with essentially the regulation of calcium in the body as a means of, in this case, promoting bone growth, and does so by using an identifier that indicates, I think, when there is a need for medical intervention.

But as I understand it, the patent has nothing to do with the underlying medication itself; that is, the abaloparatide drug product, that that's a preexisting medication. But this is really a patent directed toward the administration of the drug, and it looks as if we have really just three terms that are in dispute.

So it being a *Markman* hearing, there is also a question of "Who gets to go first," but probably we should let the party defending the patent go first and then hear the other side.

MS. WANG: Thank you, your Honor. And we do have hard copies of the slides, which I believe are being handed up.

(Document handed to the Court.)

MS. WANG: Thank you, your Honor. Sophie Wang on behalf of Radius and Ipsen.

And there are, in fact, three terms there are in dispute today, but before I get to the first term, which I will handle, and then I will hand it off to my sister, Ms. McGillycuddy, to handle the next two terms, I do want to spend about five minutes just to give your Honor a little bit of context about these patents because there are actually four patents that are asserted in this litigation that are at issue. So it's not just one patent directed to a particular method of treatment.

So this case concerns the branded product Tymlos, which is Radius' only commercial product. And Tymlos, as your Honor noted, is a treatment for osteoporosis. It was approved in 2017 for that indication for postmenopausal women. It was also approved this past December for treatment of male osteoporosis.

And osteoporosis is a bone disease. It's marked by loss of bone mass. It leaves patients with weaker bones overall and more susceptible to bone fractures.

Now, as your Honor noted, Tymlos itself, abaloparatide, the compound, was an older compound. But the innovations that are at issue in this case concern the particular compositions and formulations of abaloparatide that

ultimately were approved by the FDA.

So Tymlos is abaloparide. It's a 34-amino acid peptide. And the important part about abaloparatide is actually its formulation for use in this multi-use injection pen that you see on Slide 3.

The novelty of this particular formulation is that it remains stable, particularly at room temperature. So it allows a patient to take the Tymlos dose, which actually is a regime of about 30 single daily doses, and take it for the whole time, 30 days, and the peptide remains stable in the pen the entire time.

The way that Tymlos works at a very high level is that because it is formulated to be injected every single day, the abaloparatide, once it's injected into the body, can actually go and bind to cells that are in your body that will actually form new bone.

THE COURT: Question.

Does the patient inject herself, or must a doctor administer the injection?

MS. WANG: The patient can inject themselves, your Honor.

And that's the beauty of the pen, is that, again, it contains enough Tymlos in it to be stable for 30 days. So you don't have to refrigerate it. You can take it with you when you travel, and you can administer the dose to

yourself. And upon injection, then the abaloparatide works with the cells in your body to basically build new bone.

Now, again, the innovations in this case, the first three patents at issue, talk about those compositions and the formulations of abaloparatide that enable this type of use, the stable compositions.

But the last patent at issue, which actually is relevant to the first term, is dealing with a different innovation entirely. And that is the innovation of the beta-Asp10 impurity, the discovery of that particular impurity.

Now, in the course of developing Tymlos, Radius was the first to discover the existence of this particular impurity. And it's called "beta-Asp10" because it's actually a structural change in the molecule that happens at the tenth amino acid in the molecule, which is an A-S-P, an Asp, aspartic acid.

THE COURT: Is the ASP10 technically an isomer?

MS. WANG: It can be referred to as an isomer. It's a conformational change. So it looks like -- if you look at the slide, it basically is the same exact components of molecule. It's just flipped essentially in a different configuration. And because of that, it actually is incredibly difficult to detect. And before Radius found it, that's why it was previously unknown, because people didn't

know to go look for it.

So the way that Radius detected it, and this is relevant again for the first term, is through a series of experiments that involved an analytical methodology referred to as "liquid chromatography." And I won't go into the full details of this, but at a very high level these types of methods allow you to separate out components within a sample, such as, for example, the impurity from the actual drug product, and then depict it essentially on a graph or a chromatogram.

And the way that this works -- again, there are many features and components here which are relevant to the first term. But the way that it works is that there is a solution in the beginning, a mobile phase solution -- sometimes it has a buffer in it; sometimes it doesn't, there's all sorts of things this can go into it -- that gets pumped through a column. And as this sample gets added, it's carried in through that column through the solution, and as it moves through the column, the actual individual components interact with the column and move at different speeds.

So as they move through, they are actually able to be separated out from one another, and when they pass through the column at the very end, they actually go through a detector. And each time a particular component is detected, it registers as a peak on the chromatogram at the end.

At a very high level, this is the sort of methodology that was used to discover this particular impurity.

Now, the most important thing, however, is that the '208 patent where this particular impurity is discussed is not limited to particular methodologies. Because what the Radius inventors also realized was that in order for you to have a formulated drug product that is suitable for administration into a patient, that drug product can only have up to a certain amount of this impurity, or else there are concerns with efficacy and potency. And the number they registered was maximum 5 percent of this particular impurity and in other embodiments even down to .5 percent.

And that leads me to the four patents that are at issue here that are on your Slide 8.

So again, the first three patents that we talked about in the very beginning are directed to the storage-stable abaloparatide compositions, those that can be used in that type of pen and maintain their stability for a period of time, as well as methods of treatment using those compositions.

The last patent, the '208 patent, is directed to the beta-Asp10 impurity and again describes not only methods of detecting beta-Asp10 but also formulated drug products that compromise that sort of maximum acceptable amount of the impurity.

So with respect to the three disputed terms that are at issue and turning to the first term, this term is, "wherein the suitability of the formulated abaloparatide drug product for administration to a subject has been established by a method comprising: detecting and quantifying the presence of less than or equal to 5 percent or less than or equal to 1 percent beta-Asp10 of the total peptide content in the formulated abaloparatide drug product."

Now, this term shows up in claims 14 and 15 of the '208 patent that are on Slide 11.

And claim 14, as you can see, is directed to a formulated abaloparatide drug product. And that product has a number of characteristics, but the dispute centers around that second "wherein" clause that's highlighted on Slide 11 and specifically the underlying portion of that clause, "a method comprising."

Orbicular's position is that this clause should be further limited to a very specific method embodiment that uses an aqueous buffer that has a pH range of between 6 to 10 and that it has that pH range prior to mixing with any other additional solvents.

Now, none of those words are in the claims themselves, and as the Federal Circuit and this court have repeatedly cautioned, any time you have a proposed construction that has a lot of words in it that are not in the claim, you

should be a little bit weary. And in this case there's absolutely no reason to limit the term this way.

But to understand exactly what Obicular is trying to do, if you go back to the description of the methodology that I mentioned that Radius actually used to discover this particular impurity, again there are many, many features and parameters in these methods, and many of them are actually discussed in the specification. You can use different solutions, a different mobile phases, multiple mobile phases, different types of columns.

Orbicular wants to limit the entire patent, including these formulated drug product claims, to a single embodiment focusing on the blue solution, the Mobile Phase 1; that that solution has to have within it an aqueous buffer that has a pH range of 6 to 10, and it has to have that prior to mixing with any other additional mobile phase solvents.

So the entire methodology they want limited to that particular use of that particular solvent.

And again, importantly, this shows up in a formulated drug product claim. It's not a method claim.

Now, your Honor is well familiar with the case law with respect to claim construction, so I won't belabor the point. But there is a heavy presumption that a term carries its ordinary and customary meaning. And there are only two exceptions to this rule. One, where the patentee acts as

her own lexicographer; and, two, where the patentee has set out and disavowed the full scope of the claim term either in the specification or in the prosecution history. And both standards are exacting. There is a high bar for fining disavowal or lexicography, and that bar is simply not met here.

In fact, as Orbicular conceded in their brief, what they're asking for is generally a disfavored approach. The Federal Circuit disfavors writing in limitations from the specification. The Federal Circuit won't even do it if the only thing that's disclosed is that single embodiment. The only way they would do it is if the patentee actually demonstrates a clear intention to limit the claim scope "using words or expressions of manifest exclusion or restriction." And they can't point to anything like that in the '208 patent.

So we start with the claim language.

There are three independent claims in the '208 patent. Claim 14, which we just looked at, is directed to a formulated abaloparatide drug product. It does not have any of the method details that is in Orbicular's construction.

Similar language, however, is found in claims 1 and 9 of the '208 patent, and those are where the patentee has expressly decided to claim particular methods.

I should note, however, that even these methodologies

that are claimed are slightly different from what Orbicular is actual trying to impose into claim 14 because these actually talk about different pH ranges. They are 7 to 9 and 7.5 to 8.5.

(Reporter interrupts.)

MS. WANG: So the doctrine of claim differentiation tells us that it is improper to take a limitation from one independent claim and import it into another independent claim. And that makes perfect sense because patents are found to, and they can, claim multiple different inventions.

And this is consistent with the specification. The title of the patent itself tells us that this patent talks about different types of inventions, formulations, as well as methods of testing, storing, modifying, and using same."

And this is distinguishable from the cases that Orbicular relies on where patents that have titles and description that are just limited to one invention were found to, in fact, be limited to those in the claims.

We don't have that here. We have a patent that's very clear that it has multiple inventions.

And with respect to the each of those categories, the patent is replete -- the specification is replete with descriptions of formulated drug product and formulation embodiments. And none of these are limited to any particular methods of testing or method features that

Orbicular is trying to now impose on claim 14.

And even when you get to the descriptions of the methods that are in the specification, including the parts of the specification on Slide 18 that Orbicular relies upon, it's actually not accurate to say that this entire patent is limited to only one method.

Because, in fact, if you look at Slide 19, in the same passage that Orbicular relies upon in columns 3 and 4 of the '208 patent, there are actually multiple descriptions of other methods in terms of method pHs, solvents, buffers that are used.

So Orbicular relies on what's highlighted in yellow on Slide 19, which is that -- first of all, it says, "In certain embodiments, the pH of the buffer used in a binary eluent is about pH 6 to 10."

They then pull from the next sentence, which actually comes from "in certain other embodiments," the rest of their construction, which is that the pH has to be prior to mixing with another solvent.

What they ignore is what's highlighted in blue, and again across the entire package but specifically in blue, in other embodiments that pH refers to the entire solution phase, which includes the combination of solvents. So certainly not prior to mixing with additional solvents.

And they provide no explanation as to why they've

cherry-picked essentially these two parts from two different embodiments within the specification to now read into claim 14.

Left with this intrinsic evidence, they now turn to the prosecution history.

And on Slide 21 you can see the relevant prosecution history that's been laid out in the parties' briefing. But the critical point from this slide is that the claims that became claims 14 and 15, the formulated drug product claims, were not added until February of 2021. And the reason that's important is Orbicular relies heavily on statements that were made to the Patent Office in December of 2020.

Now, again, that has a number of flaws with it. First, the fact that those statements had nothing to do with the pending formulated drug product claims because they didn't exist at the time. All of the claims in December of 2020 were directed to methods, and they were directed to specific methods, again because the patentee correctly identified that there were certain methods they could claim. And when they limited their remarks in 2020 regarding the -- when they discussed their remarks in 2020 discussing the prior art, they repeatedly referenced those methods "as claimed."

There's no identification in the record anywhere that the applicants intended to extend these statements about the prior art relating to those pending method claims to claims

that did not even exist at that time.

In contrast, when the new drug product claims were added in February of 2021, those formulated drug product claims that ultimately became claims 14 and 15, the applicants were crystal clear. In the February 2021 remarks, they stated repeatedly that, "following an examiner interview" they had chosen to narrow their invention in this patent, what they're claiming, being two buckets of claims. First, methods for detecting beta-Asp10; and, second, and the use of that "or" is really important here, drug products that contain less than that requisite amount of beta-Asp10.

And the applicants noted that those claims relate again to the suitability of the formulation -- the formulated drug product, as opposed to any particular method that's used to detect beta-Asp10.

In fact, in March of 2021 when the examiner actually issued the Notice of Allowance, the examiner actually put in an amendment at the very end where the examiner took this exact term that's at issue and moved it from a dependent claim into the independent claim.

And when the examiner was doing this, looking right at these words, the examiner did not write in any additional limitations relating to pH or acqueous buffers or any of that, even though that language was perfectly accessible to the examiner.

Instead, what we got was the exact language that's in this term, which is, "a method comprising." That is all that this term requires. That is the plain and ordinary meaning of this particular term, and there is no basis in the intrinsic evidence or otherwise to limit it to any other features of the methods as Orbicular is trying to do.

And with that I'll reserve, unless your Honor has any question, the rest of my time for rebuttal.

THE COURT: No. The slides were very helpful.

MS. WANG: Thank you.

THE COURT: Do you want to go claim by claim or side by side?

MR. POLLACK: I'm happy to do whatever your Honor prefers. I'm happy to give my presentation of this term, or, if you would like to do all three first, I'll do whatever your Honor prefers.

THE COURT: I think we had planned to do all three, so maybe we'll just --

MS. WANG: We're actually fine with term by term.

THE COURT: All right.

MR. POLLACK: It will require me to switch out the hardware, if that's okay.

(Pause in proceedings.)

MR. POLLACK: Good afternoon, your Honor. As I think you heard before, my name is Alan Pollack of the

Windels Marx firm, and I will be presenting the claim construction positions of the defendant, Orbicular, this afternoon.

Collectively I think my time would run under 30 minutes, but we will break it up however your Honor prefers.

THE COURT: We're not going to hold you exactly to the 30 minutes.

MR. POLLACK: Well, your Honor's welcome to ask any questions at any time, of course, as well.

I will refer to both plaintiffs as just "Radius." There's actually Radius and Ipsen, I understand that, but for convenience I'll just call them "Radius" collectively.

There are three disputed terms, as we've already established over here. We have those three terms shown together here. I'll first present just the first term, which -- I'll call it the detecting and quantifying term. And as you heard, the Court has already heard, that appears in claim 14 and 15 of the '208 patent.

And the constructions are on the screen here in the top row. And, of course, the Radius construction is simply a plain and ordinary meaning. Our construction has more detail. They're, of course, not pleased with the amount of detail that's there, and I will respond to some of the bases for that as well.

Let me skip forward to the rest of that.

The next slide just -- it's not specific to that term only, but it does set forth the landscape of the four patents that are in dispute.

And as your Honor has already heard, there are four separate patents in suit. Collectively, 91 claims have been asserted against us at this time. And although we're only presenting three terms, which in my experience is rather surprising given the high numbers of claims here, all of the terms that we will be talking about are shown on this slide together with the application and the patents from which they come.

I did want to note also there is a fourth set of claim terms which we've called the "pharmacokinetic terms." That's shown at the bottom right of this slide. They all come from the re-examination of the '444 patent.

We will not be saying much about them today because the only dispute about them is whether they are indefinite, and your Honor has already told us that indefiniteness will be decided at a later time. So I don't intend to say much about that now.

There is an indefiniteness issue with one of the other terms, but I'll get to that when we address that term directly.

And the term that I'll talk about now is, indeed, the detection and quantification term that Radius' counsel has

also discussed. The proffered constructions of both parties are shown on this slide here which your Honor has already seen.

But before we get to the issue of whether it's appropriate to write in limitations that we propose, we understand the Radius people are quite displeased with that, and I understand that, I think there is a more fundamental issue that needs to be resolved. And it's not resolved by simply saying "plain and ordinary meaning."

That more fundamental dispute is does this claim limitation have any method requirement at all? Not necessarily the specific one that we have suggested, but does it have a method, some method, any method, required at all?

Because I was quite confused reading their briefing. I don't know what their position on that is. If you look at the two excerpts from their brief on the left of Slide 6, those excerpts suggest to me that they think this claim, despite the fact that the word "method" appears in the middle of it, they think it has no method requirement whatsoever; not just the specific method that we suggest, but any method.

And we've also heard this morning from Radius' counsel about some supposed important difference between the fact that they have method claims and formulation claims.

This, of course, is indeed a formulation claim, but it has in the middle of it the word "method." And that's shown right here.

They did cite some law that said that product-by-process limitation shouldn't be imported into a product claim or a composition claim without some good reason to do that.

Well, the fact that they wrote in the words "has been established by a method comprising: Detecting, and quantifying"... that's a pretty good reason to think that there should be some method required here.

We can differ on whether it should be the specific method that we've suggested, and I do have some reasons for that I'll go over in a minute.

Before we do that, I think it's important to establish that this claim does indeed have some method requirement. You can't just ignore that. You can't leave that language out.

They have accused us of a serious claim construction infraction; writing in when you're not supposed to. They've pointed at case law we're all familiar with that the Federal Circuit disfavors that. They cited our brief. We certainly agree with that.

Nevertheless, there are occasions in which we do write in from the specification if the intrinsic record supports

that. It's our position it does. But that's arguable. I agree with that.

But what should not be arguable and what should be beyond dispute is that this claim does require some type of method. And the fact that it appears in a formulation claim doesn't discount that. Because if that is their position -- and I'm frankly not quite sure it is because I can't tell from their briefing, and that's why we were very unhappy with simply having heard from them, "plain and ordinary meaning." We don't know what they mean by "plain and ordinary meaning." Do they mean there's no method requirement at all here? I'm still not sure, and I've read their briefs many time.

But if it is their position that there's no method requirement whatsoever in this claim, despite the fact that the words "method comprising" appear in the middle of it, well, that's a far worse infraction of what they're accusing us of.

They're accusing us of writing in when we shouldn't. But if that is their position, and again I'm not quite sure it is, but if it is, they are doing something far worse, they're taking language out. They're just ignoring that.

THE COURT: I do not mean to speak for the plaintiffs in the case. But I think in response to your question, I think what they might say is that, As we see it,

the relevant claims are really not directed to a method of the detecting and quantifying the Asp10; that, right, there are claims directed to a drug formulation, which includes specific levels of Asp10.

In other words, I think they might be reading the claims a little bit differently than you are.

MR. POLLACK: Well, I think that would be an erroneous reading of the claims because the words "has been --"

THE COURT: I didn't say they would. I may be wrong. I'm just maybe translating for them --

MR. POLLACK: That is what I was trying to find out because I don't know what their position is. I don't know whether they think because this is a formulation claim that there is no method requirement whatsoever. And if that's not their position, then there's no real issue here. But I still don't know that. And that's one of the reasons why we were not happy and -- we didn't think saying "plain and ordinary meaning" was enough. It doesn't answer that question. I don't know.

And as I showed in, I think the previous slide -- I will go back.

If you look at the two quotes from their briefing on the left here, that, at least from my read of that, is they think there is no method requirement.

But if you look at the two quotes that we have on the right, it's not so much that. It's that they think there isn't a requirement for the specific method that we've suggested.

But again, even there you have to be very careful with the words that are being used because the fact that the claim may permit a method is not really the answer to the question that I'm asking.

These claims of course are claims that use the word "comprising." You can see that in the first word in the second line. So of course they permit anything, any extra thing, because they're comprising claims, so they're open-ended.

That's not the real issue. The issue is, is some method required? That's the question, and I still don't know the answer. And I think, given the words that are listed here in this claim that they chose to write, of course how else would you interpret those words? Any other interpretation you would be writing out words in the claim, which I don't understand the Federal Circuit to have ever blessed; whereas, writing in, again not what we normally do but sometimes we do, the Federal Circuit has sometimes said, good to go with that. That is okay.

And so with that I just want to turn to what the basis for our position is. You heard some of that already.

Our position is that the specification does not really describe an enormous number of different ways to do this. It describes a fairly specific set of criteria that are used to find this impurity and make the formulation without it. And those specific criteria were put into claim 1, which I acknowledge is a method claim.

And the bullet points below here lists some of those criteria. Those are the criteria that we think belong in claim 14 because those are the criteria that they were forced to put into the method claims because the examiner said, no, you have to be more specific, and they did.

And that's shown -- I'm sorry.

I should point out our construction comes from the specification. They're perfectly correct about that. And the part of the specification that it comes from is shown here. I believe they showed a similar slide.

I will also agree that some of the criteria that we are suggesting should be part of this method are not identical to those shown in Claim 1.

But, you know, you want to -- you want to take it from claim 1, that works for us, too, although I don't know why they should be upset that we're supposing a construction that is a broader range of pH than specifically claimed here. We said 6 to 10 because that was the maximum range listed in the spec. So we gave them the biggest range that

they disclosed. Why that should be a point of contention I'm not quite sure.

But, in any event, that is the source of our construction.

And we are also relying on the prosecution history, which is shown in part here, the two components of claim 1 that they were -- that they added in some of which to get over prior art are shown in the underlined portion of the claim shown here with their discussion about them.

And frankly I don't know what the answer to the question is. If these limitations were required to be added in for patentability by the examiner for this specific claim, which is not the claim we're talking about, I agree with that, why wasn't this criteria added into claim 14, or required to be added into claim 14?

THE COURT: On that issue is there any statement you can point to by the examiner stating that the limitations of claim 1 need necessarily be incorporated into claim 14?

MR. POLLACK: No, I don't believe so.

And they are correct to point out that claims 14 and 15 came into the patent application very late in the game, in our view, pretty much after the prosecution in chief was pretty much done, and, frankly, I don't have an explanation for why that was.

We regard that as an error of the examiner. Of course they disagree. Your Honor will decide what is appropriate.

That's my piece on that, and I can pass it back to them to talk about the next term if you'd like.

THE COURT: Thank you.

Ms. Wang probably wants to correct me.

MS. WANG: Very briefly, your Honor.

(Counsel conferred.)

MS. WANG: Radius has never suggested, your Honor, reading any particular terms out of the claim.

Our position is that the claim as written means what it says, which is, A formulated abaloparatide drug product comprising less than or equal to 5 percent of this beta-Asp10. That product then also has an acqueous buffer within it. That's talking about the actual drug itself, which I don't think is in dispute.

Then that product also has these two additional "wherein" clauses. First, that the formulated drug product has a concentration between 1.8 and 2.2. Again, not in dispute. And, second, where the suitability of that drug product for administration into a patient has been established by a method comprising, detecting and quantifying the presence of that less than or equal to 5 percent of beta-Asp10.

The claim is direct that way.

So we're not saying that you can have abaloparatide and simply say, Oh, I assume it's 99 percent pure and, therefore, it definitely has less than 5 percent of beta-Asp10. That's not what we're saying.

You actually have to demonstrate by some method, and it says, "a method comprising, detecting and quantifying" that particular percentage of beta-Asp10.

That's how you demonstrate the suitability of the drug product.

So we are not reading out any method. What we're actually trying to do is stay true to the claim language and not do what Orbicular is suggesting, which is now to read in particular parameters of what method you use, to specify that you have to use a method that has a pH buffer, that you have to have a method that has that buffer before you do anything else with it.

That's the disputed issue here, is Do we stay true to the term language, the claim language, that just says "a method comprising," or do we read in the extraneous features that Orbicular has tried to introduce?

And I believe my brother conceded that there is nothing in the prosecution history, no statements by the examiner, nor any statements by the applicant, that any sort of distinguishing arguments with respect to the then-pending method claims back in 2020 should be extended to apply to

the formulated drug product claims that came in 2021.

So again, nothing in this case in the intrinsic record suggests that you should import these limitations and go against the full weigh of the Federal Circuit case law that cautions against this approach. And for that reason I urge your Honor to adopt the plain and ordinary meaning of this term.

THE COURT: I'm trying to understand in a broad sense, from the inventor's point of view, what is the particular value conferred by the detection method?

MS. WANG: So if you're talking about the claims that are not at issue, your Honor. So there are method claims --

THE COURT: No, I'm interested in the invention itself --

MS. WANG: So there --

THE COURT: -- what the inventor would think was really the great leap forward.

MS. WANG: Yeah.

So there are actually -- as I mentioned at the beginning, there were two sort of major leaps, and I think it's really important to think about both.

In the first instance, again the discovery of this impurity, which we're talking about a drug that is inserted, as your Honor knows, injected into a patient daily. And

we're talking about a formulated drug product that has to be suitable for that administration.

So after the Radius inventors found the impurity -- first, there's an innovation here of actually how to find it because it is kind of difficult to find, but also recognizing that there's a certain percentage that you can have in your product that is the maximum acceptable percentage to be suitable.

And there's -- in the specification there are descriptions of how the Radius inventors determined that particular percentage and therefore created a formulated drug product that is actually manufactured and determined suitable for administration because of that particular percentage.

So those are two separate buckets of innovations.

Because again before the Radius inventors knew about that, there were -- nobody knew about the beta-Asp impurity, and so there was a risk that patients were getting abaloparatide that would not have pure -- or, actually, mostly pure abaloparatide.

So those are different buckets of innovations, and it's important to remember that it's not just limited to method of detecting.

THE COURT: Thank you. That's helpful.

MS. WANG: Thank you.

THE COURT: We're going to pass the baton to Ms. McGillycuddy, I think.

MS. WANG: Yes.

MS. McGILLYCUDDY: Good afternoon, your Honor. Bryana McGillycuddy from Choate, Hall & Stewart on behalf of plaintiffs.

Now, the next term that we're going to construe is shown here on the slide, "said composition does not contain a chemical stabilizer."

Now, this is found in dependent claim 13 of the '333 patent. Claim 13 depends from claim 1 of that patent.

So claim 1 of the '333 patent is shown here on Slide 29. Claim 1 recites, "A storage-stable composition suitable for administration to a subject"... And that composition comprises the abaloparatide peptide as well as an effective amount of a pH buffer.

Now, the claim that's in dispute here is claim 13, which depends from claim 1.

Claim 13 recites that same composition and specifies that "the composition does not contain a chemical stabilizer."

Now, the crux of the parties' dispute here doesn't center on the full scope of claim 13, but it focuses on the question of what is meant by the term "chemical stabilizer."

Now, Radius' position, your Honor, is quite simple.

It's that "chemical stabilizer" should be given it's plain and ordinary meaning, which here is informed by the definition of the broader term "stabilizer," to be a "composition which maintains the chemical stability of the peptide."

Orbicular, on the other hand, has tried to create confusion here where there really is none. And it's put forward multiple proposed constructions of what is a chemical stabilizer. And those two are shown here on Slide 29.

On the one hand, according to Orbicular's original construction, a chemical stabilizer is a "composition which maintains the chemical, biological or hormonal stability of the peptide," so not limited to chemical.

Orbicular has also put forward an alternative construction that a chemical stabilizer is a chemical, not a composition, that imparts any type of stability.

THE COURT: This is a distinction which I think would be very helpful to understand. I mean, when I look at something like "chemical stabilizer," what comes to my mind, I would say, would be adding sulfite to wine to keep it from oxidizing. That's my idea of a stabilizer. But you say, no, you mean something else here.

MS. McGILLYCUDDY: That's correct. It would be more a gasoline stabilizer, your Honor. You may be familiar

with that.

THE COURT: I used to work in a gas station, actually.

(Laughter.)

MS. McGILLYCUDDY: There you go.

So a gasoline stabilizer is a product used to stabilize gasoline -- or, excuse me, stabilize a lawnmower for long-term storage. It is not gasoline that is used to stabilize.

And I think if your Honor looks at the next slide, Slide 30, this will help inform this meaning as well.

So the guiding evidence here in resolving this dispute in figuring out how does chemical modify stabilizer is the fact that the '333 patent expressly defines the term "stabilizer," the broader term "stabilizer."

And it does so by saying "a stabilizer is a composition which maintains the chemical, biological or hormonal stability of the peptide."

So a stabilizer generally maintains certain types of peptide stability. And it separates that out into three categories based on their function. So you can therefore have a chemical stabilizer that maintains chemical stability; a biological stabilizer that maintains biological stability; and a hormonal stabilizer, which maintains hormonal stability of a peptide.

The fact that there are three different types of stabilizers that are subsumed within this broader definition of stabilizer is made clear by the identification of those three types of stability in the specification, and the fact that the definition uses the word "or," which lists them out in the alternative, showing that they have independent meaning and are not intended to be grouped together as one, which is what Orbicular is trying to do here.

Now, as mentioned at the outset, Orbicular has put forward multiple proposed constructions of "chemical stabilizer." And, to be honest, it's not clear which one they're going with. Are they going with a composition that maintains chemical, biological or hormonal stability? Are they going with a chemical that imparts any of that stability? But no matter what, Orbicular's constructions are contrary to the intrinsic evidence.

And Slide 33 here shows Orbicular's construction of chemical stabilizer in the context of that broader defined term stabilizer.

So if Orbicular construes chemical stabilizer as a chemical which maintains the chemical, biological or hormonal stability of the peptide, which is shown next to number one here on Slide 33, that's directly contrary to the intrinsic evidence, which I'll walk through next.

But you'll see in the intrinsic evidence the only

instances that "stability" and "stabilizer" are modified by the term "chemical" is in reference to its function, the assessment of the chemical stability of the peptide, which in this case, as the specification makes clear, is the ability of the peptide to maintain its chemical structure over time.

So that's what we're talking about when we talk about a "chemical stabilizer," something that is helping the peptide maintain its chemical structure and prevent against degradation.

There's not a single reference in the specification or anything else that Orbicular points to that says we're talking about a chemical that stabilizes more broadly, not a single reference.

Now, on the other hand, if Orbicular is construing "chemical stabilizer" as is shown next to this number 2 here, as "a composition which maintains the chemical, biological or hormonal stability of the peptide," Orbicular is effectively writing the definition of stabilizer to be the same as a chemical stabilizer. They're changing the defined term. They would effectively nullify the defined term "stabilizer" by doing this.

If the patentee intended to define "chemical stabilizer" instead of "stabilizer," it could and would have done that. It did not.

Now, as your Honor is well aware, the Federal Circuit has made clear that specification definitions must control.

Here the inventors expressly defined the broader term "stabilizer."

Orbicular cannot now rewrite that to be a different definition of the term "chemical stabilizer."

Now, I submit, your Honor, that the analysis could begin and end with the specification definition of the broader term and how it's clear that the defined term "stabilizer" tells us that the narrower term "chemical stabilizer" is referencing chemical stability, its function.

But the intrinsic evidence confirms that that's what's meant here.

First, there's only a few references to "chemical stability" or "chemical stabilizer" throughout the specification.

The first is the specification definition that we just discussed.

The second is when the specification evaluates chemical stability, again measured by percentage peptide remaining over time.

It's clear, as shown on Slide 34 here, that when saying "chemical stability" and "chemical stabilizer," what the inventors were talking about was the function of maintaining the peptide chemically. They're assessing the chemical

stability of the peptide over time. They're not talking about a chemical that stabilizes, and they're not talking about stability more generally.

On the right-hand side of Slide 34, the specification provides a list of exemplary stabilizing agents immediately following the definition of "stabilizer." And Orbicular would have stabilizing agents be limited to chemicals.

But that's not true. This list of stabilizing agents includes proteins, and that's shown here on Slide 34 where the specification says, "proteins, such as, albumin."

It's clear at the end of the day no matter how you read the specification or the file history that when the inventors were talking about chemical stabilizers they were talking about chemical stabilizers in their function in maintaining the chemical stability of the peptide over time. They were not talking about chemicals.

Now, the next argument that Orbicular makes here is that the specification conflates "stabilizer" and "chemical stabilizer." And they make that -- they manufacture that conflation to support their construction that a chemical stabilizer should be defined to be the same thing as a stabilizer.

First, it's important to note that Orbicular has not provided any evidence to support this argument, no expert declaration, nothing. It's just attorney argument, how --

excuse me, how Orbicular's attorneys interpret the specification.

Second, the intrinsic evidence makes clear that the inventors did not conflate stabilizer and chemical stabilizer to mean the same thing. The references to chemical stabilizer clearly refer to chemical stability.

Now, Example 1 of the patent, which is shown here on Slide 35, is an evaluation of chemical stability. And in this example the inventors show that you can have a stable formulation without having a chemical stabilizer.

And Orbicular points to the description of this example, which is shown in the first callout box on the right, and says -- Radius says here, "excellent chemical stability," and the "solution contains no stabilizer."

Clearly, according to Orbicular, "chemical stability" and "stability" and "chemical stabilizer" and "stabilizer" must be the same thing. But the context makes clear here, your Honor, that it's referencing a chemical stabilizer in the context of chemical stability. This entire example, an evaluation, is of chemical stability.

And if there were any doubt, which there's not, the description of Figure 1, which is what's being evaluated in Example 1 in the specification, makes clear that the no stabilizer being referenced there is no chemical stabilizer.

It's clear from the specification and the examples that

the inventors intended to separate out different types of stability and different types of stabilizers based on their function.

Example 1 is referencing chemical stability and chemical stabilizers.

Example 4 later in the patent refers to biological stability in evaluating the effectiveness of preservatives. There's no mention of chemical stabilizers or chemical stability there. That's a biological stability assessment. There's a clear delineation.

Now, lastly, Orbicular contends that the purpose of the invention is a stable composition with respect to all types of stability. And in Orbicular's view, for this reason, all references to chemical stability and chemical stabilizer must be referring to all types of stability and not just chemical stability.

And Orbicular's correct that the aim of the patent is to achieve compositions that are storage stable. But here the claim language of dependent claim 13 governs, and claim 13 discusses a narrower form of stability, a chemical stabilizer. And just because the recited purpose of the invention doesn't further break it down to chemically stable, biologically stable, hormonally stable, doesn't mean that claim 13 should be broadened out to cover all types of stability.

And beyond that, Orbicular misunderstands the concept of stability and the purpose of stability, and that's shown in Example 1 here, which shows that you can have a stable formulation without a chemical stabilizer.

Now, based on the claim language and the intrinsic evidence, it's clear that the defined term "stabilizer" is a broad term covering multiple categories or types of stabilizers. "Chemical stabilizer" is one type of stabilizer that maintains the chemical stability of the peptide, and for that reason, your Honor, we ask that you adopt Radius' proposed construction.

THE COURT: Thank you.

Mr. Pollack.

MR. POLLACK: Thank you, your Honor.

Now we'll address the second term, the chemical stability term.

And this is, in our view -- it boils down to essentially a dispute about whether chemical stability means a chemical that stabilizes, which is essentially what we say, or whether it means a stabilizer that provides only a very specific type of stability, and that's what we just heard Radius insist this claim term means.

But before we get to that, I think it's important to recognize one fact about indefiniteness. Again, I don't ask the Court decide anything about indefiniteness now, but we

insist that claim 13 is indefinite, and we believe the basis for that and our reasons for that do have a bearing on a proper claim construction, to the extent we can have one.

And the basis of that is really quite simple. If we look -- the point of all of these patents, as we understand it, is to make a compound, which had been around for a while, the abaloparatide compound, in a stable formulation because alone it was not stable enough to use in the way that people wanted to use it.

So if we look at claim 1, which is a very simple claim, it has only two limitations, and the preamble says that the formulation you end up with is a storage-stable composition.

The first part of that claim, a), the one that's boxed in red, is the abaloparatide compound, which we know is not already stable.

So if we end up with a storage-stable composition, the only other thing in this claim that can provide that stability is Element b), which is the buffer. But the buffer is also a chemical, and that to me means that the buffer must be a chemical stabilizer.

But if we go to claim 13, which incorporates all the limitations of claim 1, it says you can't have a chemical stabilizer.

So how can we have a buffer? We don't think that conflict is something that can be resolved, but we're not

asking the Court to look into that now, but it does bear on how we decide what the term "chemical stabilizer" means.

Because at the end of the day this doesn't make any sense. So for them to suggest that something is wrong or off about what we're saying, I think there's a more fundamental problem, which is this patent, or at least claim 13, doesn't make any sense because of how they use these terms. And that's partly the basis for why our construction, we believe, is the preferred one, to the extent there can be one here.

The point of this patent, as I think we already heard from Radius counsel, is to have a stable composition overall. Whether we parse that type of stability into three different components or not, the point is to have an overall stable compound. But if we look at the intrinsic record here, first at the specification, we do not find the type of specificity that we believe Radius is improperly trying to inject into this claim under the guise of suggesting that it's the plain meaning.

If we look at how -- first of all, the term "chemical stability, chemical stabilizer" never defined anywhere in the spec. The purported definition that they point to is a general definition of "stabilizer" that's shown on the left side of this slide.

And if we look at Figure 1, that purports to show the

stability of the product by measuring the amount of the abaloparatide compound that remains in its original form after the passage of a particular amount of time. That's called here "percent peptide remaining."

When they use the word "peptide," I think we can all agree we're talking about the abaloparatide peptide. So that's what -- we're measuring how much of the original stuff is still there after a certain amount of time. The more of the original stuff that's there the better. That means we have a more stable formulation. So far, so good.

And if we look at the description of Figure 1, we see the one time the term "chemical stabilizer" is mentioned outside of the claims. That's all fine.

But if we go to something like Table 6, which has a very similar sort of data set, although it's characterized a bit differently -- these are the two things that are boxed in the green on this slide -- it says, Percent initial concentration at time T equals zero.

That might be a little confusing, but it's basically the same thing as percent peptide remaining, how much of the original stuff is still there?

And here we're measuring a different version of it with something called phenol.

Phenol is an antimicrobial. That's described in the center of this slide from a portion of the specification.

And although they don't use the words "biologically stable" here, if we have to pick among the three types of stability, phenol would fall into the biological stability category. But yet it's doing the exact same thing that we saw in Figure 1. It's preserving the peptide in exactly the same way. So I'm not sure where we get this difference between the two or why that difference really matters.

And I think this is most clear from a comparison between the specification of the '770 patent and the '333 patent.

If we could just go back to this slide, which I showed originally, you can see how the '770 is related to the '333. They both originate from the PCT from 2007, and the '770 issued a bit earlier than the '333, but they're all genealogically related.

And if we look at the '770 specification, some words appear there that are different than in the '333. And highlighted sentence says, referring to the compositions of the invention, "These compositions eliminate the need for chemical stabilizers and other stabilization techniques, such as, lyophilization."

Now, what this sentence tells us is that the term "chemical stabilizers" was used by them to distinguish providing the stability by adding something like a chemical as opposed to providing stability by performing a process, a

process like lyophilization.

By the way, "lyophilization" is just a fancy science word for freeze drying. Basically it's another way to make something more stable. But it's different than adding a chemical or adding something.

And I think that's what the term "chemical stabilizer" was used to mean here. It was used to distinguish adding stuff into the formulation from doing something to the formulation.

That's what the term "chemical stabilizer" should mean, and that supports our construction and why our construction is the proper plain meaning construction, at least with the specification that we have.

And there is no response to this. I didn't hear anything from them about this at all. This was in our brief, our responsive brief. They obviously wouldn't have had a chance to comment about this in their responsive brief because they were simultaneous. But they got that brief, I don't know, a long time ago, and I didn't hear anything about that today.

So we think this is perhaps the most persuasive intrinsic evidence why we're correct to the extent that this claim can have some sort of a meaning, but, as I said in the beginning, we don't think there's really a lot of meaning to be had because we think it's inconsistent with claim 1.

And, of course, we've heard some additional discussions here this afternoon about overall drugs. The point of the patent is to be stable overall, not to have only a very specific type of stability. We're not looking for a formulation that might be hormonally or biologically stable but not chemically stable. There's no point in that. There's no point in parsing stability in the way that they're suggesting to do it here. It just doesn't make any sense. The overall point was stability of all types, not stability of one specific type.

And I think that's all I have for that term.

THE COURT: Thank you. I understand.

The third term. Ms. McGillycuddy, you are going to have to explain to me what the actual difference is --

MS. McGILLYCUDDY: Yes.

THE COURT: -- with respect to this claim.

MS. McGILLYCUDDY: If I may briefly be heard in response to my brother counsel on rebuttal for "chemical stabilizer"?

THE COURT: Yes. Go ahead.

MS. McGILLYCUDDY: Thank you very much. I promise to be brief, your Honor.

Your Honor, rather than being supported by the claim language or the intrinsic record, all we heard was attorney argument. Orbicular's again manufacturing confusion here

where none existed, and I would like to start with my brother counsel's reference to the '770 patent because he said I didn't mention it in my openings argument. And, quite frankly, your Honor, I didn't mention it because it doesn't further their construction.

They point to the '770 patent, a different patent in this family, and say that it distinguishes chemical stabilizers from other stabilization techniques. But as shown here on Slide 48, lyophilization is a method for a process that can increase the stability of the peptide. That is distinct from an agent, such as a chemical stabilizer, that can be added to the composition to maintain its stability.

Now, just because Radius distinguished in the '770 patent processes such as lyophilization from chemical stabilizers, those agents that can be added, does not mean that Radius was conflating chemical stabilizer with all types of stability or saying that chemical stabilizer must be a chemical. Instead, it was just distinguishing processes from agents.

So again, their reference to the '770 patent and this lyophilization discussion does nothing to advance their argument.

My brother counsel also mentioned the inclusion of the antimicrobial agent phenol and said that because phenol

increased the chemical stability of the formulation that was being evaluated in Table 6 in comparison to Example 1, phenol must be a chemical stabilizer. Again, we're just hearing attorney argument here. There's no evidence.

What my brother counsel failed to mention is that the parameters, the formulation components of the target of Example 1, were different from the target of the Table 6 formulation. The concentration of abaloparatide differed meaningfully. There was only .1 mg per ml of abaloparatide in one formulation; when there was 2 mg per ml in another formulation.

So it's comparing apples and oranges. You can't look at one formulation that's entirely different from another formulation and say, because that other formulation was more stable and included phenol, that phenol must be a chemical stabilizer. There's no conclusion that can be drawn there.

And lastly, your Honor, I would like to briefly address my brother counsel's indefiniteness argument. And I would just like to note for the record that the indefiniteness argument of claim 13, or the issue of indefiniteness, rather, was raised for the first time in Orbicular's opening brief. It was never mentioned during conferrals or the joint claim construction statement; but nevertheless, so the record's clear, we'll respond to it here.

The indefiniteness argument is that the buffer of claim

1 must be the same thing as a chemical stabilizer because the buffer is the only thing that imparts stability on claim 1.

Again, this is all attorney argument. There is no conflation in the patent of the term storage-stable and chemical stabilizer. We're talking about two different things here.

And it's important to note that Orbicular's problem that it's created here, this manufactured indefiniteness problem, is by taking the term "stabilizer" and conflating it with "chemical stabilizer." There's just no support for that.

The intrinsic record makes clear that claim 13's recitation of "does not contain a chemical stabilizer" is exclusive of the buffer.

If you look at Slide 47 shown here, you can see that the specification treats buffers and stabilizers as two separate things.

First, we have a description of pharmaceutically acceptable excipients, and that says they may include buffers on the one hand and, among other things, stabilizers. Two separate things.

The excerpt pulled from Example 1, which is shown in the second box here, says that you can have a solution that contains no stabilizer and only 6 millimolars acetate

buffer.

So it's quite clear that the inventors viewed the buffer of claim 1 to be distinct from the chemical stabilizer of claim 13.

And the doctrine of claim differentiation also applies here. As your Honor is aware, there is a presumed difference in meaning and scope when different terms are used. Claim 1 uses a pH buffer. That has a distinct meaning within the specification.

Claim 13 uses chemical stabilizer that must have, under claim differentiation, a different meaning and scope. And it does, is a narrow type of stabilizer that is added to the formulation.

There's simply no conflation of buffer and chemical stabilizer throughout the specification, and this confusion or, you know, inability to correlate claim 1 with claim 13 that my brother counsel mentioned, is purely of their own makings.

In closing, Orbicular has not pointed to a single reference in the specification or file history to support its construction that a chemical stabilizer must be a chemical that stabilizes things more broadly.

Radius' simple proposed construction which is grounded in the specification definition of the broader term stabilizer should apply.

Thank you, your Honor.

THE COURT: All right, "bone fracture."

MR. POLLACK: Your Honor, could I just briefly comment on a few things that she just said?

THE COURT: Yes.

We don't have to switch equipment, do we?

MR. POLLACK: No, no. no.

Very briefly, I just want to touch on a handful of things she mentioned.

She mentioned something about being unfairly surprised or, I don't know, waiver or something about the indefiniteness argument for this particular claim term.

I really don't understand that point at all.

THE COURT: Well, judging from how polished her response was, I don't think she was that surprised.

(Laughter.)

MR. POLLACK: Yes. I don't think so either.

But I find their position a bit odd, in that they are the party that seemed to be very eager to have indefiniteness rolled over for a dispute for another day. And of course your Honor decided that that would happen. So the fact that we introduced this, in their view, late, when we're not going to be deciding this issue until, I don't know, some future time, I'm not sure how this causes any problem. So that's a bit of a mystery to me.

Second, I just want to point out that I believe our logic in comparing claim 1 to claim 13 is simply unassailable. I don't understand how they can avoid that. But indefiniteness is an issue for another day.

I also want to push back a bit on their criticism that our presentation as being attorney argument. I mean, I don't see an expert here on their behalf either. They didn't submit an expert declaration about anything. We certainly did rely on parts of the intrinsic record. So I don't think that's a fair characterization of our presentation.

THE COURT: All right.

MS. McGILLYCUDDY: Hello again, your Honor.

So we are on to the third and final term, which is "said subject has a bone fracture."

THE COURT: This seems the kind of argument that Thomas Aquinas would have loved.

(Laughter.)

MS. McGILLYCUDDY: Excuse me, your Honor?

THE COURT: This is the kind of differentiation that Thomas Aquinas would have delighted in, parsing the difference between these two constructions.

MS. McGILLYCUDDY: To be honest, your Honor, the dispute between the parties isn't entirely clear to Radius either.

It's Radius' position that the term "has a bone fracture" is quite straightforward. It's a well-understood term, and its plain and ordinary meaning should apply. In our view, no further construction is necessary, but Orbicular has added 15 words, which are shown in red here in the gray box on Slide 39 that really muck up the meaning of this term, and it's unclear to us what exactly they're advancing here by saying, "when administration started"... and ..."does not include a break that occurs after administration is started."

And it's important, your Honor, to put dependent claim 8 in the context of claim 1 from which it depends. So claim 1 recites, A method of stimulating bone growth... comprising administering to a said subject a composition that has abaloparatide and a buffer.

Claim 8 says that the subject must have a bone fracture. The subject has a bone fracture when being administered that composition.

And the guiding principle of this term is one we've already discussed at length today. So I'll only touch upon it briefly. But it's that the Federal Circuit has made clear that unless the patentee has acted as his or her own lexicographer and defined a term or otherwise expressly disclaimed claim scope, the plain and ordinary meaning should govern.

This is particularly true, as we have been instructed by *Phillips*, with commonly understood words. If a word can be understood by a layperson, then claim construction just involves the widely accepted meaning of that term being imparted.

Here, the plain meaning of "has" is clear not only to a person of skill in the art but to any layperson. "Has" is well understood to have present tense meaning.

And Orbicular doesn't appear to dispute that "has" has a present tense meaning, but they have added a bunch of words that appear to change the meaning of this term "has" and make it "had."

Now, in the context of claim 1, "has a bone fracture" is just that a subject has a bone fracture when being administered. There's no further temporal limitations. That's true of the specification as well.

The only reference to this term "bone fracture" in the specification is shown here on Slide 41 where it says that these compositions are "useful in the treatment of diseases or disorders associated with deficiency in bone growth such as osteoporosis and bone fractures."

There's no point in the specification where the timing of the bone fracture is limited; no point in the specification that says the bone fracture must be present before and not after administration.

And Orbicular's moving away from the plain meaning of "has" and confusingly adds these 15 words to a simple and straightforward term.

And it's particularly problematic here because the '382 patent teaches administration of abaloparatide as a single dose or multiple doses over time.

And I have shown here on Slide 43 what the teaching of the patent is. So the plain and ordinary meaning of "has a bone fracture," in view of this teaching and the language of claim 1, is that the subject has a bone fracture at any point during the course of administration. That could be the administration of the first dose, or that could be the administration of the eighth dose.

But Orbicular is introducing complexity into this simple term. And it appears to us, your Honor, that the defendant is attempting to improperly narrow claim 8. And they're trying to say that the bone fracture can only be present at the first administration in a course of treatment and not thereafter.

And Slide 44 shows the impact of this type of construction. Under the claim language, a subject who develops a bone fracture while being administered abaloparatide, regardless of what dose number it is, will fall within the plain and ordinary meaning.

Orbicular, on the other hand, has arbitrarily decided

that the subject can only have a bone fracture when the administration started. And that's shown in the red arrow here. Anything after the red arrow would fall outside the scope of claim 8 according to Orbicular's construction.

And this is improper because it's moving away from the claim term "has" from its present tense, and for every dose after the first administration it's turning it into "had."

Your Honor, Radius' construction of plain and ordinary meaning is straightforward and simple. It's that the word "has" means what it says, that the subject has a bone fracture when being administered. There's no reason, in the specification or otherwise, to add 15 additional confusing words to this claim term.

And for that reason, unless your Honor has any further questions, I will cede the podium.

THE COURT: As I understand it, what you are saying is that, yes, there has to be a bone fracture, but if there is a series of dosages, it just has to be present during one of those administrations.

MS. McGILLYCUDDY: That's correct, your Honor.

THE COURT: Okay. I followed you then.

MS. McGILLYCUDDY: Thank you.

MR. POLLACK: I will be very brief.

I don't think there's an enormous dispute about this term. It's clearly the simplest one I think we're

discussing today.

Basically, our position is that our construction is the plain meaning, not that we're displacing it. And we want it to be very clear. Because one of the concerns I had with their construction is I don't now where their yellow arrow ended.

If you look at their Slide 44, there was a yellow arrow. I don't know where that ends. I don't know when the administration of the drug is considered to end, which was why we put in the words that we did to try and make clear what is meant by "has" in the present tense. That was the only reason we did that. Because this drug is administered in a continual way for some period of time. I don't know when they consider the administration to end.

Does it end within a day after the last dosage is given? Does it end within an hour, a year? I mean, that, to me, is an avenue for confusion.

So that was the basis for our construction, which comes from the dictionary. And I think we probably do agree with Radius' counsel that "has" has a very clear meaning to all of us. We all speak English. We don't need to consult an expert on that. We can go to any dictionary and find that out. And that what's our construction was intended to do. And also to point out that relying on the doctrine of claim differentiation, as they've mentioned a few times, if there

isn't a temporal limitation in the way that we suggest, we don't think there's as much of a meaningful distinction between claim 1 and claim 8 as there really should be.

What I heard today I think was a little different than what we saw in their briefing.

In their briefing they said there was no temporal limitation at all. Now, that one I'll push back on petty hard. But I think our construction is the better plain meaning, and the basis of it is the ordinary meaning of "has," which really shouldn't be debated.

And that's all I have with that, and unless your Honor has any other questions...

THE COURT: No.

This is all very helpful, very well presented.

Does anyone have to have the last word, or is that the last word?

MS. McGILLYCUDDY: Nothing further from the plaintiff, your Honor.

THE COURT: All right.

Good. I will take the matters under advisement. I will try not to be terribly long with a decision for you. I know I am going to be seeing you again anyway probably soon.

MR. POLLACK: Sure.

THE COURT: We will be in recess on this matter with thanks to counsel.

THE CLERK: All rise.

(Proceedings adjourned.)

C E R T I F I C A T E

I, James P. Gibbons, Official Court Reporter for the United States District Court for the District of Massachusetts, do hereby certify that the foregoing pages are a true and accurate transcription of my shorthand notes taken in the aforementioned matter to the best of my skill and ability.

/s/James P. Gibbons March 25, 2024
James P. Gibbons

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